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Russian Federation

Food and Agricultural Import Regulations and Standards

New Rules for Registration of Medical Drugs for Animals and For Feed Additives

2005

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Report Highlights:
The Ministry of Agriculture recently issued the Order “On approving the rules for the federal registration of medicinal drugs for animals and for feed additives.” The order establishes a procedure for the registration of domestic and foreign medicinal drugs for animals and for feed additives, with the exception of feed additives derived from genetically modified sources. Federal registration is required for the use of any of these products produced, imported, sold, or utilized on the territory of the Russian Federation.

Includes PSD Changes: No
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Informal translation

Order of the Ministry of Agriculture of the Russian Federation (Minselkhoz of Russia)

#48 of April 1, 2005
Registered in the Ministry of Justice of the Russian Federation on April 14, 2005.
Registration #6510

On Approving the Rules for the Federal Registration of Medicinal Drugs for Animals and For Feed Additives

In order to implement the requirements of the Law of the Russian Federation of May 14, 1993, # 4979-1 "On veterinary issues" (Journal of the Congress of the People's Deputies of the Russian Federation and the Supreme Soviet of the Russian Federation, 1993, # 24, article 857; Collection of the legislation of the Russian Federation, 2002 (part 1), # 1, article 2; 2004, # 27, article 2711; 2004, # 35, article 3607) and the Federal law of June 22, 1998, # 86 – ? 3 "On medicinal drugs" (Collection of the legislation of the Russian Federation, 1998, # 26, article 3006; 2000, # 2, article 126; 2002 (part 1) # 1, article 2; 2003, #2, article 167; 2003, # 27 (part 1), article 2700; 2004, # 35, article 3607) I direct:

1. Approve the Rules for the Federal registration of medicinal drugs for animals and feed additives (attached).
2. Rosselkhoznadzor (Russian Veterinary and Phytosanitary Surveillance Service) shall implement the Federal registration of medicinal drugs for animals and feed additives in compliance with the above-mentioned Rules.
3. Entrust Deputy Minister S.G. Mitin with exercising control over implementation of this Order.

Minister
A. Gordeyev

Attachment

Rules for the Federal Registration of Medicinal Drugs for Animals and For Feed Additives

1. Rules for the federal registration of medicinal drugs for animals and feed additives (hereinafter – Rules) were developed in compliance with the Law of the Russian Federation of May 14, 1993, # 4979-1 “On veterinary issues”, the Federal law of June 22, 1998, #86 – F3 “On medicinal drugs”, the Terms of Reference of the Ministry of Agriculture of the Russian Federation of June 28, 2004, # 315 and the Terms of Reference of the Russian Veterinary and Phytosanitary Surveillance Service, approved by the Resolution of the Government of the Russian Federation of June 30, 2004, #327.
2. The Rules establish a unified procedure of the federal registration for domestic and foreign medicinal drugs for animals (hereinafter – medicinal drugs) and feed additives (hereinafter – additives) with the exception of feed additives derived from genetically modified organisms.
3. The procedure for the federal registration of medicinal drugs and additives, which is established by the Rules, is mandatory for implementation by legal and physical entities that carry out production, sales, utilization as well as importation of medicinal drugs and additives to the territory of the Russian Federation.
4. The following items are subject to the Federal registration:
    - New medicinal drugs;
    - New additives;
    - New combinations of medicinal drugs that were registered previously;
    - New combinations of additives that were registered previously;
    - Medicinal drugs that were registered previously, but produced in different medicinal forms, or in new dosages, or with the new composition of auxiliary substances;
    - Additives that were registered previously, but produced in different medicinal forms, or in new dosages, or with the new composition of auxiliary substances;
    - Reproduced medicinal drugs;
    - Reproduced additives.
5. The federal registration of medicinal drugs and additives shall be carried out by Rosselkhoznadzor (Russian Veterinary and Phytosanitary Surveillance Service) based on the Conclusion of the “All-Russian Federal Center for Quality Control and Standardization of medicinal drugs for animals and feeds” (hereinafter – FGU “VGNKI”) within six months from the date the registration documents and the data, envisioned by the current Rules, are submitted. For the federal registration of a medicinal drug or an additive, the Applicant shall submit the following registration documents and data to the Rosselkhoznadzor:
    - Application for the federal registration of a medicinal drug or an additive;
    - Legal address of the organization-producer of a medicinal drug or an additive;
    - Name of the medical drug or the additive, including international non-patented name, scientific name in the Latin language and basic synonyms;
    - Original name of the medicinal drug or the additive, if it is registered as a trademark in compliance with the legislation of the Russian Federation on trade marks, service marks and names of locations of the product origin;
    - List of components in the composition of the medicinal drugs or the additives as well as their quantity;

- Instruction on the use of the medicinal drug or the additive, its format being in compliance with the Federal law of June 22, 1998, # 86 – F3 "On medicinal drugs";
- Quality certificate for the medicinal drug or the additive;
- The medicinal drug or the additive production data;
- The medicinal drug or the additive quality control methods;
- Results of the medicinal drug or the additive clinical testing;
- Results of the medicinal drug or the additive pharmacological or toxicological testing;
- Results of the veterinary testing;
- Samples of the medicinal drug or the additive to conduct expert evaluation of its quality;
- Proposals on the medicinal drug or the additive pricing;
- Documents confirming registration of the medicinal drug or the additive if it was registered outside the boundaries of the Russian Federation.

6. Expert evaluation of the medicinal drugs and additives is carried out by FGU "VGNKI"* upon agreement of the parties. Expert evaluation of the medicinal drugs and additives includes:
   a) Specialized evaluation of the registration documents aimed at developing substantiated Conclusion on the efficiency, safety and quality of the medicinal drug or additive;
   b) Testing of the samples of the medicinal drug or additive for compliance with the requirements of the normative-technical documentation on the medicinal drug or additive quality control and reproducibility of the suggested testing methods.
7. Based on the expert evaluation results, FGU "VGNKI" sends the substantiated Conclusion on the possibility or impossibility to register the medicinal drug or additive to Rosselkhoznadzor.
8. Based on the results of consideration of the documents and based on the expert evaluation of the FGU "VGNKI", Rosselkhoznadzor makes the decision on the registration or substantiated refusal to register the medicinal drug or the additive. In case of submittal of the incomplete set of registration documents and data, as well as in case of doubts about the quality or credibility of the materials submitted, the procedure of the federal registration is suspended for the period of time not exceeding three months.

   In case of non-submittal by the applicant of the necessary materials about the medicinal drug or additive within the established period of time as well as in case of detecting non-credibility of the materials submitted, the applicant shall be refused federal registration of the medicinal drug or additive.

   Based on the decision on registration, the Rosselkhoznadzor shall issue to the Applicant a document of the established format about the federal registration for every (medicinal) form of the medicinal drug or additive for the period of five years, approved instructions on how to apply medicinal drug or additive and agreed normative-technical documentation.
10. Registration of the medicinal drug or additive may be suspended in case it is detected that a medicinal drug or additive has a side effect or in case certain data about it are received that were not known at the point in time it was being registered.
11. During the term of validity of the document on the federal registration, the applicant shall report any changes that are being planned to be introduced into the registration documents and submit exhaustive information on the reasons for these changes and

* Article 16 of the Law of the Russian Federation of May 14, 1993 # 4979-1 "On veterinary issues".

their impact on the efficiency, safety and quality of the registered medicinal drugs or additives, including the changes in technology and location of production.

12. Six months prior to the end of the term of validity of the document of federal registration, the applicant shall have the right to submit an application to register the medicinal drug or an additive for a new term.
13. The registered medicinal drug or the additive is entered into the Federal Register of the medicinal drugs and feed additives.